UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/196,867	11/20/1998	BRIAN KELSALL	14014.0312	9637

23859 7590 06/26/2003

NEEDLE & ROSENBERG P C
127 PEACHTREE STREET N E
ATLANTA, GA 30303-1811

EXAMINER	
VANDER VEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	90

DATE MAILED: 06/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

40

Office Action Summary	Application No. 09/196,867	Applicant(s) KELSALL ET AL.	
	Examiner F. Pierre VanderVegt	Art Unit 1644	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 April 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,8 and 10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8 and 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The Examiner in charge of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to F. Pierre VanderVegt, Ph.D. in Art Unit 1644.

Claims 9 and 11-13 have been canceled previously.

Claims 1-6 are newly canceled.

Claims 7, 8 and 10 are currently pending.

1. In view of applicant's amendment filed April 7, 2003, only the following grounds of rejection are maintained for the reasons made of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-8 and 10 stand rejected under 35 U.S.C. 102(b) as being anticipated by Rosen et al.(WO 89/04174, published May 18, 1989).

It was previously stated: "Rosen et al teach a method of administering an antibody (M1/70 as well as 5C6) with specificity for CR3 for the treatment or prophylaxis of inflammatory, autoimmune and hypersensitivity diseases, and in particular inflammatory bowel disease, and consequently its symptoms (see entire article, including the Abstract and second paragraph of page 8 and also page 9) as recited in the instant claims. Though the referenced teachings do not explicitly teach that administration of antibodies directed to CR3 down regulates interleukin-12 in a subject or treats the interleukin-12-induced inflammatory response, down regulation of interleukin-12 in a subject and treatment of an interleukin-12-induced inflammatory response would be inherent properties effected by administration of antibodies against CR3. Therefore the referenced teachings anticipate the claimed invention."

Applicant's arguments filed April 7, 2003 have been fully considered but they are not persuasive. Applicant contends that the claimed method of treating inflammatory bowel disease cannot be considered inherent over the Rosen et al reference because the reference does not specifically show the successful treatment of inflammatory bowel disease with anti-CR3 antibodies, asserting that the treatment of inflammatory bowel disease is the "missing element" of the teachings of Rosen. Applicant cites several instances of Case Law in an attempt to bolster this position. The Examiner respectfully disagrees with Applicant's position. As acknowledged by Applicant on page 6 of the response, Rosen provides an anti-

CR3 antibody that inhibits the recruitment of myelomonocytic inflammatory cells. Rosen shows in Example 2 (pages 27-37) "the extent to which T-cell dependent inflammation induced by specific antigen (ag) challenge in sensitized mice" (page 27, first paragraph) and asserts on page 29 (last paragraph) that "[t]here is convincing evidence that the footpad DTH measured in the mouse following intravenous immunisation with a low dose of SRBC is a good model of T-lymphocyte-mediated recruitment of myelomonocytic cells." Accordingly, the model is accepted in the art as one for investigating treatment of inflammatory responses in general. Furthermore, as referenced in the previous Office Action, Rosen teaches that treatment with anti-CR3 antibodies is relevant to the treatment of inflammatory bowel disease as a particular embodiment of the invention as evidenced by the second paragraph of page 8:

> " The antibodies may be used for treatment or prophylaxis of diseases or disease states which arise as the result of recruitment of myelomonocytic cells to inflammatory stimuli or as the result of complications of the adhesion of myelomonocytic cells to endothelium, such as increased vascular permeability. Diseases in which the recruitment of myelomonocytic cells appear to be involved in their development and or pathogenesis include inflammatory, acute hypersensitivity and autoimmune diseases. **In particular the antibodies of the invention may be used in the treatment and prophylaxis of diseases involving recruitment of myelomonocytic cells in delayed type hypersensitivity reactions mediated by T-lymphocytes such as chronic inflammation and drug induced hypersensitivity reactions. Further examples of such diseases include rheumatoid arthritis, immune vasculitis, glomerulonephritis, and inflammatory bowel disease**. Examples of other diseases which may be treated using the antibodies of the invention are: endotoxin toxicity, gout, immune complex diseases, multiple sclerosis and other inflammatory demyelinating diseases, neutrophil dermatoses, the after effects of myocardial infarction, adult respiratory distress syndrome, disseminated intravascular coagulation syndrome, emphysema, asthma, and the Arthus phenomenon. The antibodies of the invention may be used in treatment and prophylaxis in relation to these and similar diseases. It will be appreciated, however, that it may not be desirable to use the antibodies of the invention in disease states caused by rapidly proliferating acute infectious agents such as some types of bacteria" (emphasis added for clarity).

Rosen further teaches (page 9, 6th paragraph) that the antibodies are also for formulation as medicaments for the *in vivo* treatment of inflammatory conditions:

> "Furthermore, in a seventh aspect, the invention includes the use of an anti-CR3 specific antibody in the preparation of a medicament for inhibiting the recruitment of myelomonocytic cells to inflammatory stimuli."

Accordingly, contrary to Applicant's position, Rosen does indeed comprise the "missing element," the treatment of inflammatory bowel disease with an anti-CR3 antibody. While Rosen does not use or disclose the same model as that employed by Applicant, the use of anti-CR3 antibody to treat inflammatory bowel disease would be recognized by one of ordinary skill in the art as being inherent in the teachings of Rosen in that inflammatory bowel disease is an autoimmune disease or disease state that arises as the result of recruitment of myelomonocytic cells to inflammatory stimuli, an event which Rosen shows is modulated by the administration of anti-CR3 antibodies.

In their simplest form, the present claims are drawn to administering a CR3 ligand, such as an anti-CR3 antibody, for the treatment of an inflammatory response and practice of the claim requires no more than administering same to a subject. While the preamble recites "inflammatory bowel disease," the preamble does not result in a manipulative change in the method of Rosen and the Court held that, "[p]reamble language in claims of patents directed to administration of anticancer drug are expressions of purposes and intended results, and as such are non-limiting, since language does not result in manipulative difference in steps of claims" *Bristol-Myers Squibb Company v. Ben Venue Laboratories* 58 USPQ2d 1508 (CAFC 2001).

Conclusion

3. No Claim is allowed.

4

. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
June 23, 2003

PHILLIP GAMBEL, PH.D
PRIMARY EXAMINER
TECH CENTER 1600
6/24/03